

106TH CONGRESS
2D SESSION

S. 2520

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of certain covered products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 9, 2000

Mr. JEFFORDS (for himself, Mr. WELLSTONE, Ms. SNOWE, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of certain covered products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicine Equity and
5 Drug Safety Act of 2000”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) The cost of prescription drugs for Ameri-
9 cans continues to rise at an alarming rate.

1 (2) Millions of Americans, including medicare
2 beneficiaries on fixed incomes, face a daily choice be-
3 tween purchasing life-sustaining prescription drugs,
4 or paying for other necessities, such as food and
5 housing.

6 (3) Many life-saving prescription drugs are
7 available in countries other than the United States
8 at substantially lower prices, even though such drugs
9 were developed and are approved for use by patients
10 in the United States.

11 (4) Many Americans travel to Canada or other
12 countries to purchase prescription drugs because the
13 medicines that they need are unaffordable in the
14 United States.

15 (5) Americans should be able to purchase medi-
16 cines at prices that are comparable to prices for
17 such medicines in other countries, but efforts to en-
18 able such purchases should not endanger the gold
19 standard for safety and effectiveness that has been
20 established and maintained in the United States.

21 **SEC. 3. IMPORTATION OF COVERED PRODUCTS.**

22 Chapter VIII of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 381 et seq.) is amended—

24 (1) in section 801(d)(1), by inserting “and sec-
25 tion 804” after “paragraph (2)”; and

1 (2) by adding at the end the following:

2 **“SEC. 804. IMPORTATION OF COVERED PRODUCTS.**

3 “(a) REGULATIONS.—

4 “(1) IN GENERAL.—Notwithstanding sections
5 301(d), 301(t), and 801(a), the Secretary, after con-
6 sultation with the United States Trade Representa-
7 tive and the Commissioner of Customs, shall promul-
8 gate regulations permitting importation into the
9 United States of covered products.

10 “(2) LIMITATION.—Regulations promulgated
11 under paragraph (1) shall—

12 “(A) require that safeguards are in place
13 that provide a reasonable assurance to the Sec-
14 retary that each covered product that is im-
15 ported is safe and effective for its intended use;

16 “(B) require that the individual, or phar-
17 macist or wholesaler, importing a covered prod-
18 uct complies with the provisions of subsection
19 (b) or (c), as appropriate; and

20 “(C) contain such additional safeguards as
21 the Secretary may specify in order to ensure
22 the safety of patients in the United States.

23 “(3) SAFEGUARDS.—In determining safeguards
24 for a covered product under paragraph (2)(C), the
25 Secretary shall consider the adequacy of the regu-

1 latory structure of the exporting country to ensure
2 the safety and effectiveness of the covered product.

3 “(4) RECORDS.—Regulations promulgated
4 under paragraph (1) shall require that records re-
5 garding importation described in subsections (b) and
6 (c) be gathered and maintained by the Secretary for
7 a period of time determined to be necessary by the
8 Secretary.

9 “(b) PERSONAL BAGGAGE.—

10 “(1) IN GENERAL.—The Secretary shall pro-
11 mulgate regulations that permit an individual to im-
12 port into the United States a covered product in per-
13 sonal baggage.

14 “(2) REGULATIONS.—Regulations promulgated
15 under paragraph (1) shall require an individual im-
16 porting a covered product to—

17 “(A) affirm in writing that the product is
18 for personal use of the individual;

19 “(B) seek to import an amount of the
20 product appropriate for personal use, such as a
21 3-month supply; and

22 “(C) provide to the Secretary—

23 “(i) the name and address of a health
24 professional licensed to prescribe drugs in
25 the United States that is responsible for

1 treatment with the product, or evidence
2 that the product is for the continuation of
3 a treatment begun in a foreign country;

4 “(ii) a description of the product, in-
5 cluding the name, the amount being im-
6 ported, and the price paid for the product;

7 “(iii) information indicating the des-
8 tination of the product;

9 “(iv) information indicating the date
10 on which and the place where the product
11 was purchased;

12 “(v) the name, address, and telephone
13 number of the importer; and

14 “(vi) any other information that the
15 Secretary determines is necessary to en-
16 sure that the product being imported is
17 safe and effective for its intended use, and
18 to ensure that the Secretary maintains the
19 ability to track an imported product that is
20 found to be counterfeit, expired, subpotent,
21 or otherwise unsafe or ineffective for its in-
22 tended use.

23 “(c) REIMPORTATION.—

24 “(1) IN GENERAL.—The Secretary shall pro-
25 mulgate regulations that permit a pharmacist or

1 wholesaler to import into the United States a cov-
2 ered product that meets the requirements of sections
3 501, 502, and 505, and was manufactured in a
4 State and exported, or in an establishment reg-
5 istered under 510.

6 “(2) REGULATIONS.—Regulations promulgated
7 under paragraph (1) shall require a pharmacist or
8 wholesaler to provide to the Secretary—

9 “(A) a description of the product, includ-
10 ing the name, the amount being imported, and
11 the price paid for the product;

12 “(B) information indicating the destination
13 of the product;

14 “(C) information indicating the date on
15 which and the place where the product was pur-
16 chased;

17 “(D) the name, address, and telephone
18 number of the importer, and the professional li-
19 cense number of the pharmacist or wholesaler;

20 “(E) information demonstrating to the sat-
21 isfaction of the Secretary that the product
22 being imported was manufactured in a State or
23 at an establishment registered under section
24 510; and

1 “(F) any other information that the Sec-
2 retary determines is necessary to ensure that
3 the product being imported is safe and effective.

4 “(d) STUDY AND REPORT.—

5 “(1) STUDY.—The Secretary shall conduct, or
6 contract with an entity to conduct, a study on the
7 imports permitted under this section, taking into
8 consideration the information received under sub-
9 sections (a), (b), and (c). In conducting such study,
10 the Secretary or entity shall evaluate the safety and
11 purity of the products imported, and other patent
12 and trade issues that may have an effect on the
13 safety or availability of such products .

14 “(2) REPORT.—Not later than 5 years after the
15 date of enactment of this section, the Secretary shall
16 prepare and submit to Congress a report containing
17 the study described in paragraph (1).

18 “(e) CONSTRUCTION.—Nothing in this section shall
19 be construed to limit the statutory, regulatory, or enforce-
20 ment authority of the Secretary relating to importation
21 of covered products, other than the importation described
22 in subsections (a), (b), and (c).

23 “(f) LIMITATION.—Information collected pursuant to
24 this section shall be subject to the provisions of section

1 522a of title 5, United States Code (commonly known as
2 the ‘Privacy Act of 1974’).

3 “(g) DEFINITIONS.—In this section:

4 “(1) COVERED PRODUCT.—The term ‘covered
5 product’ means a prescription drug under section
6 503(b)(1).

7 “(2) PHARMACIST.—The term ‘pharmacist’
8 means a person licensed by a State to practice phar-
9 macy in the United States, including the dispensing
10 and selling of prescription drugs.

11 “(3) WHOLESALER.—The term ‘wholesaler’
12 means a person licensed as a wholesaler or dis-
13 tributor of prescription drugs in the United States.”.

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